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EXAMINER

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PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte VAN LE HUYNH, MICHAEL J. SCOTT, and
DERRICK JOHNSON

Appeal 2011-005910
Application 10/802,314
Technology Center 3700

Before DEMETRA J. MILLS, JEFFREY N. FREDMAN, and
STEPHEN WALSH, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a sewing ring attached to a periphery of a prosthetic heart valve. The Examiner rejected the claims as anticipated and obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

Statement of the Case

Background

“Prosthetic heart valves are used to replace damaged or diseased heart valves” (Spec. 1, l. 15). In “prosthetic valves, a biocompatible fabric-covered suture or sewing ring or cuff on the valve body (mechanical) or stent (tissue-type) provides a platform for attaching the valve to the annulus of the particular valve being replaced” (Spec. 1, ll. 27-29).

The Claims

Claims 1-21 are on appeal. Claims 1 is representative and reads as follows:

1. A sewing ring attached to a generally annular periphery of a prosthetic heart valve having an inflow end and an outflow end, comprising:
a suture-permeable ring attached to the heart valve periphery and configured to pivot from a first position extending generally toward the outflow end of the valve to a second position extending generally toward the inflow end of the valve, wherein first and second positions are stable such that the sewing ring is bi-stable.

The issues

- A. The Examiner rejected claims 1-8 and 11-19 under 35 U.S.C. § 102(b) as anticipated by Totten¹ (Ans. 3-4).
- B. The Examiner rejected claims 9 and 20 under 35 U.S.C. § 103(a) as obvious over Totten and Huynh² (Ans. 4).

¹ Totten et al., US 4,477,930, issued Oct. 23, 1984.

² Huynh et al., US 5,928,281, issued Jul. 27, 1999.

C. The Examiner rejected claims 10 and 21 under 35 U.S.C. § 103(a) as obvious over Totten and Reichart³ (Ans. 4-5).

A. *35 U.S.C. § 102(b) over Totten*

The Examiner finds that Totten teaches “a tubular fabric with a stent frame and a ring insert” (Ans. 3). The Examiner finds that “the Totten suture ring is configured to pivot or move between two positions since it is made of an elastomer . . . which illustrates that the sewing ring can pivot about the edge” (Ans. 4). The Examiner finds that “Totten discloses the sewing ring to be pliable or suture permeable (col. 4, line 16), thus it can be interpreted to be bi-stable because of its flexibility and placement at a seam or edge as seen in Fig. 8 and since it will not deform permanently, it is stable when it moves” (Ans. 4).

Appellants “maintain that Totten does not disclose or suggest a sewing ring, or valve having a sewing ring that is configured to pivot or move between bi-stable first and second positions, respectively, toward the inflow end and the outflow end of the valve. Note that bi-stable means that the element moves between two stable positions” (App. Br. 4).

Appellants contend that

Totten clearly states that the sewing ring is encouraged to lie smoothly when the skirt portions are pulled over it so as to be angled somewhat upwardly toward the post (outflow) end of the stent. This obviously means that the fabric skirt is pulled tight to maintain the illustrated angle of the sewing ring. While the pliability of the sewing ring of Totten will permit it to flex outward from the angled position shown, there is simply no basis for asserting that it can pivot or

³ Reichart et al., US 4,626,255, issued Dec. 2, 1986.

move into another stable position angled in the opposite direction (toward the inflow end)

(App. Br. 5).

Appellants contend that “even if the Examiner considers the claim terms at issue to be functional, they must still be considered to carry patentable weight. The question of whether the sewing ring in Totten, et al. inherently pivots or moves to different positions has already been addressed in prior amendments, and the conclusion was that it doesn’t” (App. Br. 8).

The issue with respect to this rejection is: Does the evidence of record support the Examiner’s conclusion that the sewing ring in Totten is bi-stable as required by claim 1?

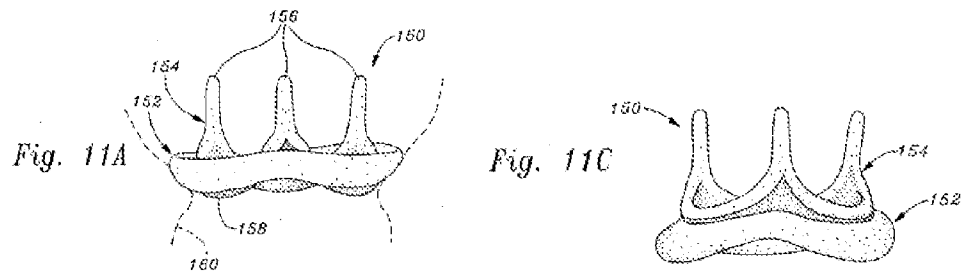
Findings of Fact

1. The Specification teaches that:

Because of the novel connection between the sewing ring 152 and stent 154, the two positions shown in Figures 11A/13A and 11C/13B are bi-stable. Specifically, the band 172 of the insert 160 creates a generally frustoconical sewing ring 152 that can be inverted between orientations extending toward the outflow end and the inflow end. The resiliency of the insert 160 means that the outer circular edge 164 is stretched and placed in tension as it passes between the two positions, thus biasing the insert one way or the other.

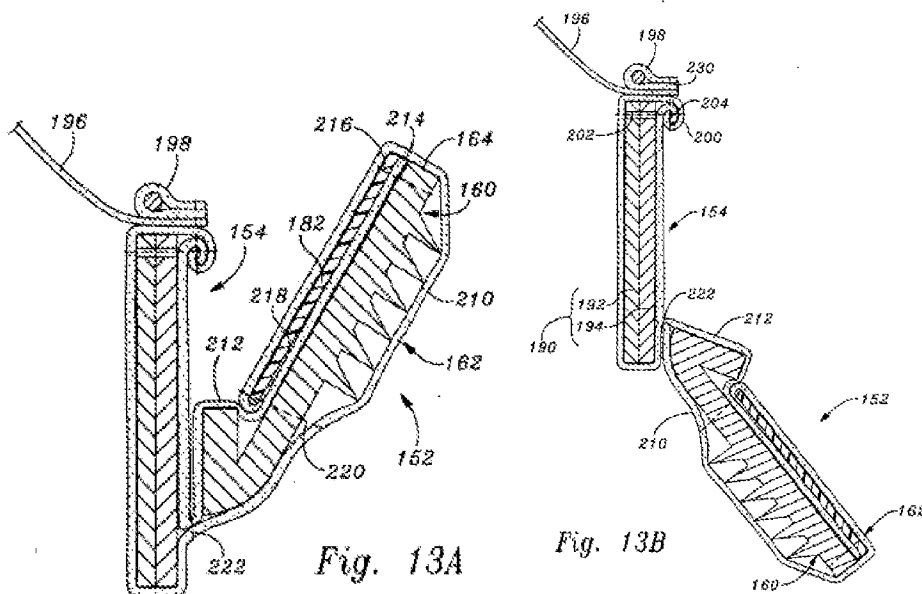
(Spec. 16, ll. 13-18).

2. Figures 11A and 11C of the Specification are reproduced below:



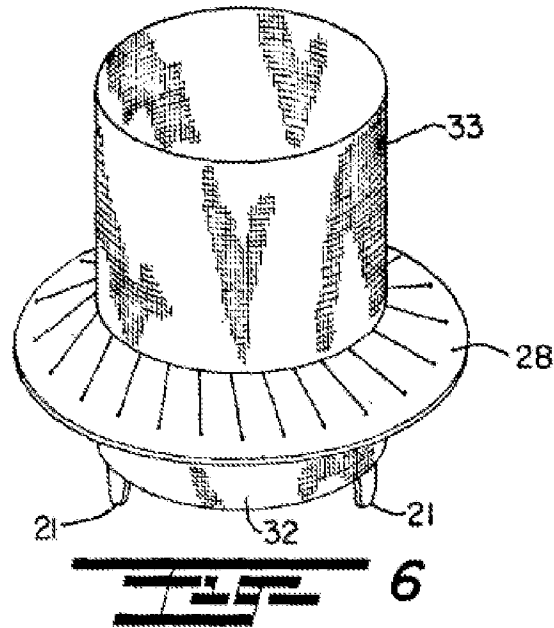
“Figures 11A-11C are elevational views of a stent/sewing ring subassembly of an exemplary aortic or pulmonic heart valve of the present invention illustrating conversion of the sewing ring between two bi-stable positions” (Spec. 6, ll. 9-11).

3. Figures 13A and 13B of the Specification are reproduced below:



“Figures 13A and 13B are cross-sectional views through the stent/sewing ring subassembly of Figures 11A-11C illustrating in more detail the sewing ring in the bi-stable positions” (Spec. 6, ll. 14-16).

4. Figure 6 of Totten is reproduced below:



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“FIG. 6 is a view illustrating the first step in the anchoring of the sewing ring to the base of the stent” (Totten, col. 3, ll. 20-21).

5. Totten teaches that a “sewing ring **28** is positioned in outer surrounding relation to the base of the stent and in a manner to be described is integrated into the valve by the fabric covering so as to serve as a secure means of implantation” (Totten, col. 4, ll. 8-11).

6. Totten teaches that the “ring **28** may be composed of cloth, e.g., felt or a compliant elastomer, e.g., silicone elastomer which, upon grafting or implantation, will together with the covering **14**, form a suitable base for fibrous ingrowth” (Totten, col. 4, ll. 12-15).

7. Totten teaches that the “the ring is sufficiently pliable as to conform to irregular openings but will assure a snug fit and seal with the wall of the annulus to which it is secured” (Totten, col. 4, ll. 16-18).

8. Totten teaches that

to encourage the ring to lay smoothly when the skirt portions are pulled over it in a manner to be described and so as to be angled somewhat upwardly toward the post end of the stent, a corner **42** is trimmed off of the inner edge so as to form a beveled edge along the upper corner of the flat surface portion **40**.

(Totten, col. 5, ll. 47-53).

Principles of Law

“A single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation.” *Perricone v. Medicis Pharmaceutical Corp.*, 432 F.3d 1368, 1375 (Fed. Cir. 2005).

“Inherency ... may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient.” *MEHL/Biophile Int’l. Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999).

Analysis

The dispute centers on whether the sewing ring of Totten inherently satisfies the functional requirement of claim 1 for a bi-stable sewing ring.

We begin with claim interpretation of the term “bi-stable”. The Specification specifically discusses the term “bi-stable” explaining that the two positions shown in figures 11A or 13A are represent one stable position and that the positions show in figures 11C and 13B represent an alternate stable position for the sewing ring (FF 1-3). The Specification explains that a “bi-stable” sewing ring can be “inverted between orientations extending toward the outflow end and the inflow end” (Spec. 16, ll. 15-16; FF 1).

We conclude that the term “bi-stable” is reasonably interpreted in light of the Specification as requiring the sewing ring to be invertable between two orientations, toward the outflow or inflow ends, where the ring will remain in the selected orientation unless altered by the artisan (FF 1-3).

Totten teaches a sewing ring which is attached to the generally annular periphery of a prosthetic heart valve and which has an inflow end and an outflow end (FF 4-8). Totten teaches that the “ring **28** may be composed of cloth, e.g., felt or a compliant elastomer, e.g., silicone elastomer which, upon grafting or implantation, will together with the covering **14**, form a suitable base for fibrous ingrowth” (Totten, col. 4, ll. 12-15; FF 6).

The Examiner finds that “because of the structural design of Totten’s sewing ring being placed at an edge and is pliable or flexible it is fully capable of moving between two positions about the edge. As a result this would be bi-stable according to Appellant’s definition of bi-stable” (Ans. 5).

We are not persuaded. As we interpret the term “bi-stable”, the term requires more than the ability to temporarily move between two positions, which is a feature of any elastomeric material. Instead, as read in light of the Specification, “bi-stable” also requires that the ring will remain in a selected position until inverted or changed by the artisan as already discussed above.

In order to properly invoke the inherency doctrine, the Examiner must provide evidence or reasoning to suggest that the product being claimed is necessarily identical to the product of the prior art, and that the products are identical insofar as shown by the available evidence. *MEHL*, 192 F.3d at 1365. Here, the Examiner has failed to provide any evidentiary basis or

scientific reasoning which would demonstrate the sewing ring of Totten is capable of being placed into a first stable position and then, upon action by the artisan to alter or invert the sewing ring, also remain stable in a second, different, position.

The evidence of record in Totten does not suggest that the sewing ring of Totten is capable of being placed into two alternate, different, stable positions. (FF 4-8).

Conclusion of Law

The evidence of record does not support the Examiner's conclusion that the sewing ring in Totten is bi-stable as required by claim 1.

B. 35 U.S.C. § 103(a) over Totten and Huynh

This rejection relies upon the underlying anticipation rejection over Totten which we reversed above. Having reversed the anticipation rejection over Totten for a failure to teach "that the sewing ring is bi-stable" as required by claim 1, we necessarily reverse this obviousness rejection further including Hunyh as Hunyh also does not teach a "bi-stable" sewing ring.

C. 35 U.S.C. § 103(a) over Totten and Reichart

This rejection relies upon the underlying anticipation rejection over Totten which we reversed above. Having reversed the anticipation rejection over Totten for a failure to teach "that the sewing ring is bi-stable" as required by claim 1, we necessarily reverse this obviousness rejection further including Reichart as Reichart also does not teach a "bi-stable" sewing ring.

SUMMARY

In summary, we reverse the rejection of claims 1-8 and 11-19 under 35 U.S.C. § 102(b) as anticipated by Totten.

We reverse the rejection of claims 9 and 20 under 35 U.S.C. § 103(a) as obvious over Totten and Huynh.

We reverse the rejection of claims 10 and 21 under 35 U.S.C. § 103(a) as obvious over Totten and Reichart.

REVERSED

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